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SUBJECT: THAILAND PREPARING COMPULSORY LICENSE FOR HIV/AIDS DRUG

(U) This document is sensitive but unclassified, please protect accordingly.

11. (U) This is an action request, see paragraph 9.

12. (SBU) Contacts at the Thai Department of Intellectual Property (DIP) told Embassy that the Ministry of Public Health (MoPH) may announce on December 1 that they plan to pursue a compulsory license for efavirenz, an antiretroviral used to treat HIV-positive patients. The announcement would be timed to coincide with World AIDS Day on Friday.

13. (SBU) Merck & Co., a U.S.-based pharmaceutical manufacturer, holds the patent for efavirenz in Thailand and distributes it locally under the trade name Stocrin. Efavirenz is a first-line AIDS drug, used primarily for the five or ten percent of patients who have had an adverse reaction to other first-line combinations. Thailand widely uses a domestically produced generic antiretroviral known as GPO-vir to treat its large HIV-positive population; substituting efavirenz greatly increases the cost per patient. Merck estimates purchases of efavirenz account for approximately 25 percent of expenditures on all antiretrovirals in Thailand.

14. (SBU) Article 51 of the Thai Patent Act spells out procedures for a compulsory license. The Act allows for an RTG ministry or department to "exploit any invention under any patent" for a variety of reasons, including "for the sake of other public interest", the justification the RTG will most likely use. Merck's local legal counsel believes that the MoPH must apply to the DIP to issue the compulsory license and enter into royalty negotiations in advance of issuing the license. The DIP, on the other hand, asserts that under Thai law, MoPH can publicly announce its plans to issue a compulsory license and negotiate the royalties afterwards. Article 31 of the WTO TRIPS agreement would normally require MoPH to first request authorization from Merck to produce or import under "reasonable commercial terms", however, DIP says MoPH plans to skip that step using exceptions under Article 31(b) for "public non-commercial use". The lead actor in importing generic product or ingredient would be the Government Pharmaceutical Organization, a revenue-earning state-owned enterprise whose activities may not qualify as public non-commercial use.

Why this drug? Why now?

15. (SBU) Merck's local representatives are perplexed why the MoPH

has decided to break their patent on efavirenz. As a middle-income country with a greater than one percent prevalence of HIV cases, Thailand qualifies for Merck's lowest price offered under its pricing policy. Merck reports to us they sell the drug at a no-profit price to NGOs, approximately 1000 baht per month (USD 27.50), less than half the price sold at in other middle income countries such as China and Brazil. Merck also sells to the government for 1300 baht per month (USD 35.80), the higher price reflecting additional local costs imposed by the RTG.

16. (SBU) It is unclear yet whether the MoPH would seek to import a generic version of the drug or produce it locally. Merck believes an Indian generic firm may be able to supply efavirenz at a slightly lower cost, but believes the savings would be minimal and hardly worth the effort. Contacts at the Government Pharmaceutical Office say they would need approximately a year to perform the necessary testing and receive approval to begin domestic production. However, MoPH believes GPO could eventually produce a generic copy of efavirenz for 30 to 50 percent less cost than the original drug.

17. (SBU) According to a MoPH source we believe credible, local public health NGOs instigated the proposal for the compulsory license and may be pushing the idea as much as a political test as for the possible cost savings to AIDS patients. Although the MoPH's Department of Disease Control initially rejected the idea, the NGOs succeeded in submitting their proposal directly to the Minister. There still appears to be a lack of consensus within the MoPH on the wisdom of pursuing a compulsory license and it is not yet clear whether a final decision has been made to push ahead with the plan. DIP has expressed its own reservations and is sensitive to how a compulsory license could affect Thailand's image regarding intellectual property protection.

18. (SBU) Embassy has been in contact with officials at Ministry of Commerce and Ministry of Foreign Affairs to ensure they are aware of

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MoPH activities and the full implications of any actions they may take. We understand an MoPH meeting will take place November 29 to discuss the issue further.

19. (SBU) Embassy requests Washington agency guidance on how to proceed and what message we should communicate to the RTG on this matter. We note that during FTA negotiations with Thailand the issue of pharmaceutical patents was highly controversial and engendered large protests. Thailand is rightly proud of its efforts to slow the spread of AIDS and the Thai public looked dimly on the FTA's possible effects on access to antiretrovirals. AIDS organizations and public health activists hold widespread sympathy in and out of the government and we suspect a compulsory license would meet with public approval. A compulsory license case would be watched closely both in Thailand and globally to gauge USG reaction and commitment to the public health provisions in the WTO. We are under no illusion that any USG action to prevent a compulsory license could be kept out of the public eye.

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